

APPLICANT(S): LEWKOWICZ, Shlomo et al.  
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### REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicant asserts that the present invention is statutory, new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

#### Status of the Claims

Claims 73-77, 88 and 89 are pending in the application, with claims 78-87 having been withdrawn.

Claim 88 has been amended herein, and new claims 90 and 91 have been added. Applicants respectfully assert that no new matter has been added.

#### Rejections Under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected claims 73-75, 77 and 88 under 35 U.S.C. § 103(a), as being unpatentable over U.S. Patent No. 6,330,464 to Colvin, Jr. et al. in view of Japan Patent Publication No. JP 05200015 to Ueda et al. Applicants traverse the Examiner's rejection.

The Examiner maintains that Colvin, Jr. et al. disclose admitting a first endo-luminal sample in an interaction chamber, which includes an indicator immobilized thereon for reacting with an endo-luminal sample resulting in an optical change, the reaction occurring in the reaction chamber, and that Colvin, Jr. et al. disclose illuminating the interaction surface and imaging the optical changes in the interaction surface with an optical system, the interaction surface being transparent in the wavelength of illumination. The Examiner states that Colvin, Jr. et al. fails to disclose pumping the sample through a first opening into an interaction chamber, discharging the sample through a second opening and replacing the sample with a new sample. The Examiner further maintains that Ueda et al. discloses a method for determining body lumen conditions including pumping a sample through a first opening (4) into an interaction chamber, discharging the sample through a second opening (5) and replacing the sample with a new sample.

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According to the Examiner, it would have been obvious to modify the chamber of Colvin, Jr. et al. to include an interaction chamber in relation to a first and second opening as taught by Ueda et al. and to apply the technique of collecting a sample within chamber through a first opening and discharging the sample through a second opening as taught by Ueda et al.

Colvin, Jr. et al. teach an optical-based sensor for detecting the presence or amount of an analyte, the sensor having a sensor body with a source of radiation and a detector embedded therein, and indicator molecules located on the outside surface of, or proximate the surface of, the sensor body that interact with emitted radiation. At least one optical characteristic of the indicator molecules varies with analyte concentration, for example, the level of fluorescence of fluorescent indicator molecules or the amount of light absorbed by light-absorbing indicator molecules can vary as a function of analyte concentration. Radiation emitted or reflected by the indicator molecules enters and is internally reflected in the sensor body, and the detector within the sensor body generates both indicator channel and reference channel signals to provide an accurate indication of the concentration of the analyte.

The Examiner is correct that Colvin, Jr. et al. fails to disclose pumping the sample through a first opening into an interaction chamber, discharging the sample through a second opening and replacing the sample with a new sample. However, the Examiner is NOT correct that Colvin, Jr. et al. disclose admitting a first endo-luminal sample in an interaction chamber, which includes an indicator immobilized thereon for reacting with an endo-luminal sample resulting in an optical change, the reaction occurring in the reaction chamber. To the contrary, nowhere in Colvin is an interaction chamber taught or even suggested. Instead, Colvin, Jr. et al. disclose an interaction surface, as stated by the Examiner in the very next sentence of the Office Action, that is illuminated and it is optical changes in the illumination surface that are imaged with an optical system.

The Examiner refers to elements 14', 14 as being the interaction chamber and to the specification of Colvin, Jr. et al. at column 6, lines 26-56 as disclosing that the chamber includes an indicator immobilized thereon for reacting with an endo-luminal sample resulting in an optical change. According to Colvin, Jr. et al. at column 6, lines 26-56, item 14 in FIG. 1 is "a matrix layer that is coated over the exterior surface of the sensor body 12, with fluorescent

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indicator molecules 16 distributed throughout the layer" (emphasis added). Similarly, according to Colvin, Jr. et al. at column 18, lines 10-24 and the text describing FIGS. 14-17, item 14' is an indicator membrane that can include indicator molecules that are sensitive to a particular analyte, such as for instance fluorescent indicator molecules that are sensitive to oxygen, and that are contained within a material that is permeable to that analyte (a parallel reference membrane 14" may include the same indicator molecules within a material that is not permeable to that analyte).

However, as defined by Merriam-Webster's Online Dictionary at <http://www.merriam-webster.com/dictionary/chamber>, a "chamber" is defined as "a natural or artificial enclosed space or cavity". Nowhere do Colvin, Jr. et al. teach or suggest that matrix layer 14, which is coated onto the surface of the sensor body, contains or forms an enclosed space or cavity. Similarly, nowhere do Colvin, Jr. et al. teach or suggest that indicator membrane 14', which is apparently applied against the sensor body, contains or forms an enclosed space or cavity. It is important to note that no analyte ever enters the sensor body or a cavity thereof. Because neither the matrix layer 14 nor the indicator membrane 14' has a natural or artificial enclosed space or cavity, neither can be considered a chamber or "an interaction chamber", as required by the claims.

Applicants further note that claim 88 has been amended herein to recite a method for determining body lumen conditions in-vivo, the method comprising the additional step of:

inserting into a body lumen an in-vivo imaging device having an interaction chamber, an imager and an optical window, wherein said interaction chamber and said imager are positioned within said imaging device behind said optical window and said imager captures images of said interaction chamber.

Amended claim 88 clarifies that the in-vivo imaging device inserted into the body lumen have an interaction chamber, an imager and an optical window, and that the interaction chamber and the imager are positioned within the imaging device and behind the optical window, and that the imager captures images of the interaction chamber.

With regard to Ueda et al., the Examiner stated that Ueda et al. discloses a method for determining body lumen conditions including pumping a sample through a first opening (4) into an interaction chamber, discharging the sample through a second opening (5) and replacing the

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sample with a new sample. However, Ueda et al. do not teach that the imager captures images of the interaction chamber, as recited in amended claim 88. In fact, Ueda teaches away from the solution claimed in amended claim 88. The only "imager" disclosed by Ueda et al. is photo detector 54 in FIG. 8, which is not directed at suction path 3 (in FIG. 1), which is what the Examiner considered as comparable to the claimed interaction chamber. Ueda et al. do not use optical detecting means. Thus, Ueda et al. do not show or teach this element of amended claim 88.

Applicant also maintains that the combination of Colvin, Jr. et al. and Ueda et al., as proposed by the Examiner, would not result in a functioning method. Colvin, Jr. et al. teaches a sensor for detecting the presence or amount of an analyte, the sensor having a matrix layer 14 or an indicator membrane 14' coated onto or applied against the outer surface of the sensor body to react with the analyte, wherein no analyte ever enters the sensor body or a cavity thereof. Ueda teaches that bodily fluid enters into a chamber within the device, but the imager of Ueda et al. does not capture images of the interaction chamber and Ueda's mechanism is not appropriate for use with an optical detector, nor is there any suggestion or teaching in Ueda et al. for such a use. A skilled person has no teaching on how to adjust Ueda's mechanism to optical detection or for imaging of the cavity, or on how to adjust Colvin, Jr. et al. to detect a reaction occurring within a chamber of an in vivo device.

Accordingly, the rejection of claim 88 should be withdrawn. Claims 73-77 and 89 depend from claim 88 and include all its limitations, and the rejection of claims 73-77 and 89 should thus also be withdrawn.

In the Office Action, the Examiner also rejected claims 76 and 89 under 35 U.S.C. § 103(a), as being unpatentable over Colvin, Jr. et al. in view of Ueda et al. as applied to claim 88 and further in view of U.S. Patent No. 5,604,531 to Iddan et al. Applicants traverse the Examiner's rejection.

Applicants refer to the discussion regarding Colvin, Jr. et al. and Ueda et al. above and note that Iddan et al. do not cure the deficiencies of either Colvin, Jr. et al. or Ueda et al. with respect to amended independent claim 88. Claims 76 and 89 depend from claim 88 and include

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all its limitations. Since the rejection of claim 88 must be withdrawn, as discussed above, the rejection of claims 76 and 89 should also be withdrawn.

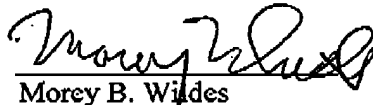
Applicants note that they have added new claims 90 and 91 directed to the method of claim 88 wherein said imager captures images of the body lumen in addition to the interaction chamber (claim 90) and wherein the imager captures images of optical changes that occur within the interaction chamber (claim 91). These new claims are not new matter and find support in the specification as filed at page 5, lines 4-9 and 17-19.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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